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1

Epidemiology Independent Expert Panel

- Held on April 19, 2000 at the request of CHPA to review the HSP results and implications for public health
- Convened under the condition that it would be independent and free to express opinions without influence of industry
- Panelist expertise in design, conduct, analysis and interpretation of case-control studies as well as hemorrhagic stroke epidemiology/neurology

2

Independent Epidemiology Expert Panel

Philip Gorelick, MD, MPH
Professor, Neurology, Rush Medical College
Lewis Kuller, MD, DrPH
Chairman, Epidemiology, Univ. of Pittsburgh
Robert Wallace, MD
Chairman, Preventive Medicine, Univ. of Iowa
Noel Weiss, MD, DrPH (chair)
Professor, Epidemiology, Univ. of Washington

3

Independent Expert Panel Review

Panelists reviewed:

- Protocol
- Interview Manual
- Case Summaries
- HSP Study Report (draft)
- Industry Statistical Assessment (*provided to investigators*)

4

Independent Expert Panel Deliberations

- Evaluated Possible Role of:
  - ***Bias***
    - Selection
    - Information
  - ***Confounding***
  - ***Chance***
    - Choice of analytical methods

5

Independent Expert Panel Conclusions

- Study represents a significant undertaking
- Numerous methodological issues limit its interpretability — chance, bias, and confounding are plausible alternative explanations for findings
- Importance of low level of participation among potential study subjects is unknown, but possibly large
- Marked differences between cases and controls (*especially independent risk factors for HS*)
- Small numbers limit ability to control for differences in characteristics

6

Independent Expert Panel Conclusions (cont.)

- Selective emphasis of subgroups may be misleading (*overall result was null*)
- No clear biologic rationale to support a causal association
- Even if association were real, population risk appears to be exceedingly small

7

8